

1091554

## 510(k) Summary

**Submitter** PharmaPac, LLC  
110 Industrial Park Road  
DeKalb, MS 39328

**Contact Person** Tom Otto  
(601) 743-9771 phone  
(601) 743-9772 fax

**Date Prepared** 29 April 2009

**Proprietary Name** PharmaPac Personal Lubricant

**Common Name** Personal Lubricant

**Classification Name** Patient Lubricant

**Predicate Device** K-Y® Brand Personal Lubricant (K955648)

### **Description of Device**

PharmaPac Personal Lubricant is a water-based personal lubricant formulated to be a non-greasy, non-sticky, non-staining clear gel-like liquid. The water-soluble formula allows this product to be rinsed off with water.

### **Intended Use**

Lubricating Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

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### **Technological Characteristics of Device Compared to Predicate**

The technological characteristics of the PharmaPac Lubricating Jelly are identical to those of the predicate devices. This includes being formulated with only United States Pharmacopeia (USP) or National Formulary (NF) ingredients, all of which are listed as "Generally Recognized As Safe" (GRAS) with the exception of Hydroxyethyl Cellulose. As also noted in the predicate device, Hydroxyethyl cellulose is listed in the FDA's Inactive Ingredient Guide and has been historically been widely used in many drug products e.g. oral syrups and tablets, also otic and ophthalmic solutions.

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### **Performance Data**

Stability of the PharmaPac Lubricating Jelly was confirmed throughout its labeled shelf life (24 Months) by an accelerated stability study for 90 days at 40°C / 75% R.H. and parallel microbial study in accordance with USP standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

PharmaPac LLC  
c/o Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

AUG 07 2009

Re: K091554  
Trade/Device Name: PharmaPac Personal Lubricant  
Regulation Number: 21 CFR §884.5300  
Regulation Name: Condom  
Product Code: NUC  
Regulatory Class: II  
Dated: July 22, 2009  
Received: July 23, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

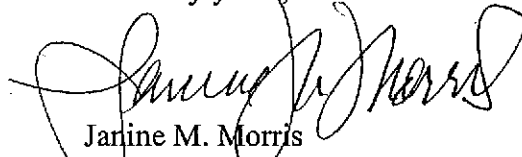
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jarline M. Morris", is written over the typed name and title.

Jarline M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K091554

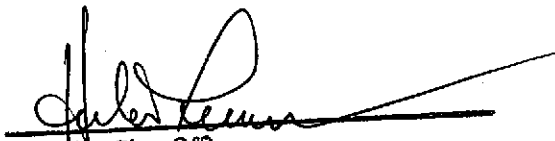
Device Name: PharmaPac Personal Lubricant

**Indications for Use:**

Lubricating Liquid is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use X  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K091554